133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

29 OCT 2018

[redacted]

Ref: H201806654

Dear [redacted]

Response to your request for official information

I refer to your request of 30 September 2018, under the Official Information Act 1982 (the Act) for:

1. *Copies of documents detailing how your Ministry has considered the implications of Part 5 (63)(2) of the Medicines Act 1981. Specifically regarding the requirement that your Officers only enter a Pharmacy premises at a reasonable time.*
2. *A copy of the protocols that you have developed to assist your staff in satisfying the part of the act that specifies that they may only enter the premises at a reasonable time.*
3. *A copy of the documents that you have developed to consider the Health and Safety risks of carrying out a spot audit on a Pharmacy when they are under resourced to deal with this and the resulting distraction of the Pharmacist.*
4. *A copy of the Protocols used by your Auditors to quantify and minimise the Health and Safety risks caused by the disruption and anxiety to a Pharmacist during a Spot Audit, when the workflow is disrupted and the Pharmacy under resourced for the intrusion.*

Information in response to your request is attached as Appendix One.

Please note this response (with your personal details removed) may be published on the Ministry's website.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely

Chris James
General Manager
Medsafe

Appendix One

1. ***Copies of documents detailing how your Ministry has considered the implications of Part 5 (63)(2) of the Medicines Act 1981. Specifically regarding the requirement that your Officers only enter a Pharmacy premises at a reasonable time.***

   Your request is refused under section 18(d) of the Act as the information is publicly available.

   The powers of officers under section 63(2) of the Medicines Act 1981 are statutory powers, and as such there is no separate document (or documents) which specifically detail how the 'Ministry has considered the implications of Part (5) (63)(2) of the Medicines Act 1981'.

   As way of clarification, 'reasonable time' is considered to be any time at which the pharmacy is open and providing pharmacy services to the public. Whilst auditing could occur on any day the pharmacy is operating, where possible, auditing activities are kept to a minimum at certain times of year, for example, between Christmas and New Year.
   The risk based inspection audits have been implemented in line with the New Zealand Health Strategy 2016, the Pharmacy Action Plan 2016 to 2020, and the Pharmacy Audit Strategy 2015-2025.

   In particular the Pharmacy Action Plan 2016 to 2020 which was developed with input from sector groups, DHBs and regulatory bodies includes 'random and risk based audits', and as such the audit model has moved to a risk based audit framework to align with this. All pharmacies are required (through the contract with DHBs) to participate in audit activities, and DHBs are supportive of this approach.

   www.health.govt.nz/publication/new-zealand-health-strategy-2016

   www.health.govt.nz/publication/pharmacy-action-plan-2016-2020

   tas.health.nz/assets/Publications/Pharmacy-Documents/Pharmacy-Audit/CPS002AuditStrategy150911.pdf

2. ***A copy of the protocols that you have developed to assist your staff in satisfying the part of the act that specifies that they may only enter the premises at a reasonable time.***

   Information in response to this request is contained in response to question one.

3. ***A copy of the documents that you have developed to consider the Health and Safety risks of carrying out a spot audit on a Pharmacy when they are under resourced to deal with this and the resulting distraction of the Pharmacist.***

   Your request is refused under section 18(e) of the Act as the documents requested do not exist.

   Medicines Control does not have a particular document which has been developed to "consider the Health and Safety risks of carrying out a spot audit on a Pharmacy when they are under resourced to deal with this and the resulting distraction of the Pharmacist".

   Whilst there is no specific document Medicines Control can advise that all auditors undergo extensive training (both internally and externally) prior to being appointed as Officers under the Medicines Act 1981 and participate in regular quality assurance activities.

Medicines Control is entrusted with ensuring that all consumers of pharmacy services are provided with a safe service and as such auditors strive to ensure that disruption is kept to a minimum.

Medicines Control expects that, due to the nature of day to day community pharmacy practice, and the interruptions that occur, the pharmacy will have robust systems in place to deal with disruptions when they arise, in order to ensure all patients receive a safe service from the pharmacy.

Medicines Control can advise that when the scope of the risk based inspection audit is selected, where possible the set include criteria which can be worked on independently, as well as others which may require more pharmacist/dispensary staff input.

To assess the perceived level of disruption, Medicines Control has sought feedback from auditees following the pilot of the risk based inspection audits which was conducted in May and June 2017, by way of online survey (specifically titled "Medicines Control Risk Based Audit Pilot Survey"). The results of this survey were published in the document "Implementing a Risk-Based Pharmacy Quality Audit Framework – Pilot Report'. Respondents were asked to select from a scale of strongly agree to strongly disagree to the statement "Disruption to activities was minimal during the site audit" to which the majority (66%) of respondents either agreed or strongly agreed.

A copy of this document was previously provided to you in response to your request H201804039.

Auditees are able to discuss their concerns with a senior member of the Medicines Control team during the audit if they wish.

Feedback regarding audit practice is welcomed by Medicines Control and feeds into our quality improvement activities.

4. ***A copy of the Protocols used by your Auditors to quantify and minimise the Health and Safety risks caused by the disruption and anxiety to a Pharmacist during a Spot Audit, when the workflow is disrupted and the Pharmacy under resourced for the intrusion.***

Information in response to this request is contained in response to question three.